

PATENT COOPERATION TREATY



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference KI78ZP3849	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEAA16)	
International application No. PCT/PL 03/00023	International filing date (day/month/year) 17.03.2003	Priority date (day/month/year) 27.08.2002
International Patent Classification (IPC) or both national classification and IPC B01L3/02		
Applicant PZ HTL SPLKA AKCYJNA et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
- ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:
- I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 04.02.2004	Date of completion of this report 09.11.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Smith-Hewitt, L Telephone No. +49 89 2399-2995 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/PL 03/00023**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*):

Description, Pages

1, 2, 6-9 as originally filed
3-5 received on 12.10.2004 with letter of 05.10.2004

Claims, Numbers

1-6 received on 12.10.2004 with letter of 05.10.2004

Drawings, Sheets

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

see separate sheet

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	2-4,6-8,10
	No: Claims	1,5,9
Inventive step (IS)	Yes: Claims	-
	No: Claims	2-4,6-8,10
Industrial applicability (IA)	Yes: Claims	1-10
	No: Claims	-

2. Citations and explanations

see separate sheet

1. Re: Item I

1.1 The basis for the amendments submitted is not clear for the following reasons:

1.2 The method described in the present claim 1 is too vague. The closest embodiment to the claim (including a calibration correction) is described on p. 8 of the description as originally filed. Furthermore, there are several contradictions between the wording of the present independent claim and the content of the description as follows:

1.2.1 No mention is made in the description of calculation of a preliminary value of the set volume. The description mentions on p.6-7 "*Current position of the adjustment screw (10) in the form of an information on the number of pulses counted by the optical system (18) is transferred to the electronic system (20). The electronic system (20) compares the signal corresponding to the position of the adjustment screw (10) with the values of the points from the standard aspiration table, which in the form of the standard aspiration table has been earlier input to its memory, assigns to the position of the adjustment screw (10) the value of the liquid being aspirated, and displays it on the display (21).*"

It is thus clear from the description that no calculation is taking place, but rather a comparison with previously stored values is occurring. Article 34(2) PCT is thus contravened as new subject matter has been introduced.

1.2.2 The description of the generation of the pulses in claim 1 is too vague. The only apparent method of counting pulses described in the present application includes an optical detection system (18), which is not mentioned in the present claim. An essential feature of the embodiment described on p.6-7 has thus been omitted. Article 34(2) PCT is contravened.

1.2.3 Furthermore, there is no mention in the application as originally filed of a "calibration correction" being introduced to the pulses counted in the electronic system. Page 8, l.17-18 mentions "*taking into account the correction for calibration*". However, this correction is taken into account for the read out of the display. No mention of "a deviation" from "a calculated value" is mentioned in the original application. Article 34(2) PCT is thus contravened as new subject matter has been introduced.

1.2.4 No basis for the procedure described by the final two lines of the amended claim 1 can be found in the description (Article 34(2) PCT), especially as no

reference to "a value of true sampling" can be found.

- 1.3 In fact, the amended claim appears to have been formulated based upon page 3 of the applicant's letter of 26.05.2004. However, the technical features (e.g. the two sensor system, the storage of a correction table, rounding the corrected value, polynomial calculation) mentioned in said letter as referring to the "invention" are not actually present in the application as originally filed. A closer inspection of the method described in the bridging paragraph of p.6-7 confirms this opinion.
- 1.4 As the amended claim 1 is not allowable under Article 34(2) PCT, the IPER must therefore be based on the original claims as filed.

2. Re: Item V

- 2.1 Independent claims 1, 5 and 9 as originally filed are interpreted (Article 6 PCT) as follows:

A method of pipette calibration, whereby:

- a. An aspiration table is input into the memory system as a standard set of points.
- b. The adjustment screw of a manual pipette is turned to regulate the length of a plunger stroke.
- c. The position of the screw is detected
- d. A corresponding signal is sent to the electronic system
- e. The signal is compared with the standard table points and the value of the aspired liquid volume is assigned.
- f. The aspired liquid volume is displayed on the display.

- 2.2 The above steps a.-f. may be read onto the disclosure of D1 (US 5998218 A, col.2, l.50 - col.3, l.40 and col.11, l.39 - col. 12, l.16 in conjunction with Fig.11). A "calibration map" may be considered to be equivalent term to an "aspiration table" or "aspiration function". Fig. 3 in conjunction with col.5, l.40 - col.10, l.12 shows the technical features of the device. Claims 1,3,5,7 and 9 cannot be considered novel in the sense of Article 33(2) PCT.
- 2.3 Document D2 (PL 325795 A), cited by the applicant, is also novelty destroying for the present claims 1, 5 and 9. Although a translation of this document has not been provided, the description of the document on p.3 of the present application suffices as proof. The scope of claims 1, 5 and 9 may be read onto this description. [It must be noted that a "multinomial" is also a set of points.]
- 2.3 The additional subject matter of claims 2-4, 6-8 and 10 represent further developments of the display function of the pipette which would seem obvious to the person skilled in the art (Article 33(3) PCT), especially in the light of D2.

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Further, the Polish patent application No. P.325795 describes a calibration method for a pipette comprising a housing in the form of a handle, and a shaft with a plunger slid by a knob through an adjustment screw, wherein the volume of aspired liquid is set manually by turning the adjustment screw in and out to set the length of the operational stroke of the plunger in the shaft, the position of the adjustment screw is detected, and the signal corresponding to the position of the adjustment screw is sent to an electronic system, in which memory standard aspiration curves are previously stored in the form of a multinominal of n -th degree, and then the signal corresponding to the position of the adjustment screw is compared with one of the aspiration curves, and the position of the adjustment screw is assigned to the value of the aspired volume of liquid which is displayed on the display.

(Summary of the Invention)

According to the present invention, in the method of pipette calibration, an aspired liquid volume is manually set by turning in and out the adjustment screw regulating the length of the operational stroke of the plunger in the shaft, where a preliminary value of the set volume is calculated basing on pulses counted in an electronic system, which are generated during the turning of the adjustment screw, a calibration correction is introduced to the pulses counted in the electronic system, which takes into account a deviation from the calculated value, and it is displayed on the display the set volume value which takes into account the calibration correction, as well as a marker indicating a turning direction of the adjustment screw, and then the adjustment screw is turned according to the direction indicated by the marker, and it is assigned to the value displayed on the display a value of true sampling. Preferably the marker indicating the turning direction of the adjustment screw is displayed to assign a displayed value to true sampling value with a minimal difference.

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Preferably the calibration correction is determined basing on the pulses counted in the electronic system and the aspiration table.

Preferably it is used as the marker indicating the turning direction of the adjustment screw a marker placed in a read-out field of the set volume on the display.

- 5 Preferably it is used as the markers indicating the turning direction a marker of increasing the set volume and a marker of decreasing of the set volume, both following the last figure displayed on the display, of the calculated sampling value. Preferably a point of the expected position of the adjustment screw is signalized by missing the marker on the display.

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5 The advantage of the methods according to the invention is the ease of pipette calibration for various types of liquid and aspiration conditions, and various types of applied tips, with reference to the pipette aspiration table or pipette aspiration function earlier input into the memory of the pipette electronic system, and possibly modified. Moreover the solution according to the invention enhances the accuracy of the set volume for required value displayed on the display, and repeatability of results.

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(Brief description of the drawings)

The accompanying drawings, which are incorporated in, and form a part of the specification, illustrate embodiments of the present invention and, together with the description, serve to explain the principles of the invention. In the drawings:

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Fig. 1 shows longitudinal section of the pipette;

Fig. 2 shows front view of the pipette.

(Detailed description of the Invention)

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Reference will now be made in detail to the preferred embodiments of the invention, examples of which are illustrated in the accompanying drawings.

25 The pipette comprising a handle (1) and shaft (2) is assigned for aspirating fluid into a disposable tip (3). A plunger (4) sealed by the means of a seal (5) moves inside the shaft (2). The plunger (4), which is driven by a rod (6) pressed by the button (7) makes reciprocal movements. When the plunger (4) moves upwards, liquid is aspirated to the tip (3), and while the plunger (4) moves downwards, liquid is dispensed from the tip (3). The movements of the rod (6) are limited by two stops, i. e. the upper stop (8) limiting the move upwards, and the lower stop (9) limiting the move downwards. Hence the upper

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We claim

5 1. The method of pipette calibration, the pipette comprising a body in the form of a handle (1) and a shaft (2), wherein a plunger (4) slid by an adjustment screw (10) is arranged, and wherein an aspired liquid volume is set manually by turning in and out the adjustment screw (10) regulating the length of the operational stroke of the plunger (4) in the shaft (2), characterised in that

10 a preliminary value of the set volume is calculated basing on pulses counted in an electronic system (20), which are generated during the turning of the adjustment screw (10),

 a calibration correction is introduced to the pulses counted in the electronic system (20), which takes into account a deviation from the calculated value, and

15 it is displayed on the display (21) the set volume value which takes into account the calibration correction, as well as a marker indicating a turning direction of the adjustment screw (10), and then

 the adjustment screw (10) is turned according to the direction indicated by the marker, and

20 it is assigned to the value displayed on the display (21) a value of true sampling.

 2. The method according to claim 1, characterised in that the marker indicating the turning direction of the adjustment screw (10) is displayed to assign a displayed value to true sampling value with a minimal difference.

25 3. The method according to claim 1, characterised in that the calibration correction is determined basing on the pulses counted in the electronic system (20) and the aspiration table.

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4. The method according to claim 1, characterised in that it is used as the marker indicating the turning direction of the adjustment screw (10) a marker placed in a read-out field of the set volume on the display (21).

5. The method according to claim 4, characterised in that it is used as the
5 markers indicating the turning direction a marker of increasing the set volume and a marker of decreasing of the set volume, both following the last figure displayed on the display (21), of the calculated sampling value.

6. The method according to claim 4, characterised in that a point of the
expected position of the adjustment screw (10) is signalized by missing the marker on
10 the display (21).

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